November 2011, Volume 4, Issue 5

THE PRESCRIBER e-LETTER

Prior Authorization Requirements for Oral Fluoroquinolone Antibiotics

Levofloxacin, ciprofloxacin, and ofloxacin are generically available fluoroquinolone antibiotics that do not require prior authorization. Branded fluoroquinolone antibiotics such as gemifloxacin (Factive), moxifloxacin (Avelox), and norfloxacin (Noroxin) now require prior authorization due to their generally similar spectrum of bacterial coverage and Food and Drug Administration (FDA)-approved indications when compared to generically available fluoroquinolone antibiotics. The table below shows both branded and generic fluoroquinolone antibiotics and their shared FDA-approved indications.

Shared FDA-Approved Indications for Fluoroquinolones

Infection	Ciprofloxacin*	Levofloxacin*	Ofloxacin*	Gemifloxacin	Moxifloxacin	Norfloxacin
Acute bacterial exacerbation of chronic bronchitis	X	X	X	X	X	
Acute bacterial sinusitis	X	X			X	
Community acquired pneumonia		X	X	X	X	
Complicated intra-abdominal infections	X				X	
Prostatitis	X	X	X			X
Skin and skin structure infections	X	X	X		X	
Uncomplicated cervical and urethral gonorrhea	X		X			X
Urinary tract infections	X	X	X			X

* Available generically without prior authorization

Influenza Updates for Fall 2011

In preparation for the 2011-2012 influenza season, the FDA has approved a vaccine that will include the three most common influenza strains based on epidemiological disease surveillance. The three strains included for the current year are identical to those seen in the 2010-2011 influenza season and include:

- A/California/7/2009 (H1N1)-like virus
- A/Perth/16/2009 (H3N2)-like virus
- B/Brisbane/60/2008-like virus

The Centers for Disease Control and the Advisory Committee on Immunization Practices have recently released their recommendations for the 2011-2012 influenza season. Current recommendations are similar to previous years where individuals aged 6 months and older should receive their vaccination as soon as the vaccine becomes available and regardless of vaccination during the previous year. Similar to previous recommendations, children aged 6 months to 8 years should receive two vaccinations spaced four weeks apart during their first season of vaccination. However, due to identical strains from the previous year, children aged 6 months to 8 years will require only one dose this season if they had received a single dose last year. Recommendations for special and at-risk populations will remain the same for the upcoming season.

Fluzone intradermal is a newly FDA-approved, inactivated influenza vaccine indicated for use in patients aged 18 to 64. The vaccine is available as a single dose, preservative-free, microinjectable, prefilled syringe. In clinical trials, Fluzone intradermal was shown to provide an immune response non-inferior to Fluzone intramuscular for all three influenza strains (HIN1, H3N2, and B). The side effect profile of Fluzone intradermal is similar to that of the intramuscular vaccine with the most common reactions being redness, swelling, induration, pain and pruritus.

The formulation of oseltamivir suspension (Tamiflu) was recently changed from 12 mg/mL to 6 mg/mL. As a result, prior authorization is now required for quantities of oseltamivir 6 mg/mL suspension (Tamiflu) > 180 mL/month and > 360 mL/season (October 1st through May 31st).

The Prescriber e-Letter is an update designed to enhance the transparency and efficiency of the MassHealth drug prior-authorization (PA) process and the MassHealth Drug List. Each issue **highlights** key clinical **information and updates** to the **MassHealth Drug List**. The Prescriber E-Letter was prepared by the MassHealth Drug Utilization Review Program and the MassHealth Pharmacy Program.

Recent MassHealth Drug List Updates

Drug/Drug Class	Addition/Deletion/Change	Rationale
Antidepressants	Change in PA status; **requires PA** imipramine pamoate (Tofranil-PM) venlafaxine ER tablets	Tofranil-PM and venlafaxine ER tablets are both used in the treatment of depression. There are more cost-effective alternatives available without PA including generic antidepressants, imipramine hydrochloride, venlafaxine, and venlafaxine extended release capsules.
abiraterone (Zytiga)	Addition; **requires PA**	Zytiga is FDA-approved for the treatment of castration resistant, metastatic prostate cancer in combination with prednisone in patients who have received prior chemotherapy containing docetaxel. Due to the cost and limited indication, Zytiga requires PA.
belatacept (Nulojix)	Addition; **requires PA**	Nulojix is FDA-approved for prophylaxis in adults receiving a kidney transplant. Nulojix requires PA to ensure that it is used appropriately for FDA-approved indications.
cabazitaxel (Jevtana)	Change in PA status; **requires PA**	Jevtana is FDA-approved for the treatment of hormone-refractory metastatic prostate cancer in patients who have received prior chemotherapy containing docetaxel. Due to the cost and limited indication, Jevtana now requires PA.
desoximetasone low potency ointment (Topicort LP ointment)	Addition; **requires PA**	Topicort LP ointment is FDA-approved for the treatment of inflammatory hyperkeratotic dermatosis. There are more cost-effective alternatives available without PA including generic medium potency corticosteroids.
diltiazem 360 mg (Cardizem CD)	Change in PA status; **requires PA**	Cardizem CD is FDA-approved for the treatment of hypertension. Cardizem CD is available generically without PA in four other strengths (120 mg, 180 mg, 240 mg, and 300 mg). Two 180-mg generically available capsules can be used to equal the dosage of the branded 360-mg strength.
doxycycline monohydrate	Change in PA status; **requires PA**	Doxycycline monohydrate is available both as a generic and as a branded product. Doxycycline hyclate is available generically without PA at a significantly lower cost.
ethinyl estradiol/ drospirenone (Syeda)	Addition; does not require PA	Syeda is a generic formulation of Yasmin. It is indicated for use as a contraceptive.
ethinyl estradiol / levonorgestrel (Amethyst)	Addition; does not require PA	Amethyst is a generic formulation of Lybrel. It is indicated for use as a contraceptive.
ethinyl estradiol/ levonorgestrel (Orsythia)	Addition; does not require PA	Orsythia is a generic formulation of Seasonique. It is indicated for use as a contraceptive.
fidaxomicin (Dificid)	Addition; **requires PA**	Dificid is an oral antibiotic FDA-approved for the treatment of clostridium difficile induced diarrhea. There are more cost-effective alternatives available without PA including generic metronidazole and vancomycin.

Please send any suggestions or comments to PrescriberELetter@state.ma.us.

Recent MassHealth Drug List Updates (cont.)

Drug/Drug Class	Addition/Deletion/Change	Rationale
gabapentin enacarbil (Horizant)	Addition; **requires PA**	Horizant extended release tablets are FDA-approved for the treatment of moderate to severe primary restless leg syndrome. There are more cost-effective alternatives available without PA including generic immediate-release gabapentin, ropinirole, and pramipexole.
Fluoroquinolones	Change in PA status; **requires PA,** gemifloxacin (Factive) moxifloxacin (Avelox) norfloxacin (Noroxin)	Avelox, Factive, and Noroxin are broad spectrum fluoroquinolone antibiotics. There are generic fluoroquinolone antibiotics available without PA with similar spectrums of activity such as ciprofloxacin, levofloxacin, and ofloxacin.
herpes zoster vaccine (Zostavax)	Change in PA status; **requires PA for patients < 50 years**	Zostavax is FDA-approved for the prophylaxis of the herpes zoster viral infection in patients aged ≥ 50. Zostavax now requires PA for patients aged < 50.
(influenza vaccine) Agriflu	Deletion; no longer on the MassHealth Drug List	Agriflu has been removed from the MassHealth Drug List because it has been discontinued by the manufacturer.
(influenza vaccine) Fluzone intradermal	Addition; does not require PA	Fluzone intradermal is a newly FDA-approved, inactivated influenza vaccine indicated for use in patients aged 18 through 64. It is available as a single dose, preservative-free, microinjectable, prefilled syringe.
ipilimumab (YERVOY)	Addition; does not require PA	YERVOY is FDA-approved for the treatment of patients with unresectable or metastatic melanoma by enhancing T-cell activation and proliferation.
ketorolac nasal spray (Sprix)	Addition; **requires PA**	Sprix is FDA-approved for the short-term management of moderate to moderately severe pain that requires analgesia at the opioid level. There are more cost-effective alternatives available without PA including generic ketorolac tromethamine tablets and injection.
lenalidomide (Revlimid)	Change in PA status: **requires PA for > 30 units/month (5 mg, 10 mg) and > 21 units/28 days (15 mg, 25 mg)**	Revlimid is FDA-approved for the treatment of myelodysplastic syndrome and multiple myeloma in combination with dexamethasone. Due to the cost and specific dosing, Revlimid requires quantity limit restrictions to ensure appropriate utilization.
linagliptin (Tradjenta)	Addition; **requires PA**	Tradjenta is FDA-approved as an adjunct to diet and exercise for glycemic control in patients with type 2 diabetes mellitus. Given the similarities in efficacy and safety between other managed dipeptidyl peptidase-4 inhibitors, Tradjenta requires PA.
minocycline tablets (Dynacin)	Change in PA status; **requires PA**	Minocycline is available as both a tablet and capsule formulation. The tablet formulation is considerably more costly than the capsule formulation, which is available without PA.
nevirapine ER (Viramune XR)	Addition; **requires PA**	Viramune XR is FDA-approved for the treatment of HIV. The immediate release formulation is available without PA.
nitrofurantoin (Macrobid)	Deletion; no longer on the MassHealth Drug List	Macrobid has been removed from the MassHealth Drug List because it has been discontinued by the manufacturer.
opium tincture	Deletion; no longer on the MassHealth Drug List	Opium tincture has been removed from the MassHealth Drug List because it is not approved by the FDA.
oseltamivir suspension (Tamiflu)	Addition; **requires PA for > 180 mL/month and > 360 mL/season**	The formulation of Tamiflu was recently changed from 12 mg/mL to 6 mg/mL. As a result, PA is required for quantities of Tamiflu 6 mg/mL suspension > 180 mL/month and > 360 mL/season.

Please send any suggestions or comments to PrescriberELetter@state.ma.us.

Recent MassHealth Drug List Updates (cont.)

Drug/Drug Class	Addition/Deletion/Change	Rationale
paregoric	Deletion; no longer on the MassHealth Drug List	Paregoric has been removed from the MassHealth Drug List because it is not approved by the FDA.
peginterferon alpha-2b (Sylatron)	Addition: does not require PA	Sylatron is FDA-approved as an adjuvant treatment for melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy.
rilpivirine (Edurant)	Addition; **requires PA for >30 units/month**	Edurant represents an NNRTI with a potentially less severe side-effect profile than NNRTIs with similar costs. Therefore, Edurant requires PA for quantities > 30 units/month.
roflumilast (Daliresp)	Addition; **requires PA**	Daliresp is a selective phosphodiesterase -4 inhibitor FDA-approved for the treatment of severe COPD associated with chronic bronchitis and a history of exacerbations. There are more cost-effective alternatives including inhaled long acting β-agonists and corticosteroids available without PA.
sipuleucel-T (Provenge)	Addition; **requires PA**	Provenge is an autologous cellular immune-therapy FDA-approved for the treatment of asymptomatic or minimally symptomatic metastatic hormone refractory prostate cancer. Provenge requires PA with the "^" symbol, it will be payable through the physician's office upon PA approval.
testosterone cypionate (Depo-Testosterone)	Change in PA status; **requires PA**	Depo-Testosterone is FDA-approved for the treatment of primary hypogonadism and hypogonadotropic hypogonadism. MassHealth requires PA for all testosterone products.
testosterone enanthate (Delatestryl)	Change in PA status; **requires PA**	Delatestryl is FDA-approved for the treatment of primary hypogonadism, hypogonadotropic hypogonadism, delayed puberty, and metastatic breast cancer. MassHealth requires PA for all testosterone products.
testosterone powder	Change in PA status; **requires PA**	MassHealth requires PA for all testosterone products. Therefore, testosterone powder requires PA.
testosterone 1.62% pump (Androgel)	Addition; **requires PA**	Androgel is FDA-approved for the treatment of primary hypogonadism and hypogonadotropic hypogonadism. Currently, MassHealth requires PA for all testosterone products.
vandetanib (CAPRELSA)	Addition; **requires PA**	CAPRELSA is an orally administered kinase inhibitor FDA-approved for the treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease. Given the orphan drug status and limited indication, CAPRELSA requires PA.
vilazodone (Viibyrd)	Addition; **requires PA**	Viibyrd is FDA-approved for the treatment of major depressive disorder. There are more cost-effective alternatives available without PA including generic antidepressants.

Please send any suggestions or comments to PrescriberELetter@state.ma.us.